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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,456	08/21/2002	Israel Raleigh Lurie	Q68463	3880

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EXAMINER	
TOWA, RENE T	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 06/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,456	LURIE ET AL.	
	Examiner	Art Unit	
	Rene Towa	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 23-44 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 23-44 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 23, 26, 33-34 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Louw (US Patent No. 4,533,345) in view of Mahurkar (US Patent No. 5,836,921).

In regards to claim 23, Louw discloses a device capable of collection of a fluid sample, comprising a flexible, hollow, elongate catheter 1 extending through an opening, said catheter 1 being sufficiently flexible so as to be capable of bending and follow the conformation of an internal cavity upon encountering walls of said cavity during insertion into said cavity without damaging tissue of said cavity, said catheter 1 further being in operative engagement with a manifold 3 for axial movement to extend and retract the catheter 1 on axial movement of the manifold 3, and said catheter 1 being in fluid communication with the fluid chamber to provide a fluid flow path to and from the fluid chamber through the hollow catheter 1 (see figs. 1-2; column 2/lines 35-53; column 3/lines 18-24; column 4/lines 23-27; column 5/lines 15-30 & 65-68; column 6/lines 1-4) .

In regards to claim 26, Louw discloses a device wherein one end is sealed 18, and the catheter 1 is provided with perforations 14 in the wall thereof at or near the sealed end 10 for passage of fluid in and out of the hollow catheter 1 (see fig. 2).

In regards to claim 36, Louw discloses a device wherein said means 12 for collecting a sample of cells or cellular debris comprises a brush or brush-like device (see figs. 1-2).

Louw discloses a device, as described above, that teaches all the limitations of the claim except that Louw does not teach a device comprising a barrel and a plunger. However, Mahurkar discloses a device as follows:

In regards to claim 23, Mahurkar discloses a device capable of collection of a fluid sample, comprising a barrel 10 having an opening 15 at one end thereof, a plunger 11 operable axially within the barrel 10, said barrel 10 and said plunger 11 defining a fluid chamber having a volume which varies on axial movement of the plunger 11 within the barrel 10 and a flexible catheter 13, wherein one end of said catheter 13 is attached to said plunger 11 and the end of said catheter 13 is remote from the plunger 11 (see figs. 4 & 5).

In regards to claim 33, Mahurkar discloses a device further comprising means for rotating the plunger 11 on axial movement of the plunger within the barrel 11 of the device (see column 7/lines 48-50).

In regards to claim 34, Mahurkar discloses a device wherein said means

for rotating is adapted to rotate the plunger 11 from 90° to 360° on full axial movement of the plunger 11 within the barrel 10 (i.e. the plunger rotates according to the curvature of slot 19; see fig. 1).

Since Louw discloses a catheter device for sampling of endometrial tissue wherein the catheter is steerable through axial (i.e. by way of the manifold 3) and rotational motions (i.e. by way of the guide 5) (see fig. 1; column 4/lines 23-27; column 5/lines 41-44) and Mahurkar teaches a catheter device that is steerable through axial and rotational motions (see figs. 4-5), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Louw with a steering mechanism similar to that of Mahurkar since both mechanisms help stabilize the catheter during its insertion into the internal cavity (see Louw, column 4/lines 35-48). Moreover, merely exchanging steering mechanisms amount to a design choice. It has previously been held that changing aesthetic design is not patentable--See In re Seid, 161 F.2d 229, 231, 73 USPQ 431, 433 (CCPA 1947).

3. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Louw ('345) in view of Mahurkar ('921) further in view of Cardwell (US Patent No. 4,932,947). Louw as modified by Mahurkar teaches a device, as described above, that teaches all the limitations of the claim except that Louw as modified by Mahurkar does not teach a plunger comprising a chamber. However, Cardwell discloses a device comprising a plunger 53 that includes a chamber (see figs. 5-7; column 3/lines 57-60). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Louw as modified by Mahurkar with a plunger

similar to that of Cardwell since such a modification would amount to a design choice. It has previously been held that changing aesthetic design is not patentable--See In re Seid, 161 F.2d 229, 231, 73 USPQ 431, 433 (CCPA 1947).

4. Claims 25, 32 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Louw ('345) in view of Mahurkar ('921) further in view of Ellard (US Patent No. 5,007,903).

In regards to claim 25, Louw as modified by Mahurkar discloses a device, as described above, that teaches all the limitations of the claim except Louw as modified by Mahurkar does not teach a catheter that is provided with perforations at or near the end attached to the plunger. However, Ellard discloses a device comprising a perforation 60 near the end attached to the plunger 50 (see fig. 3). Since Louw as modified by Mahurkar teach catheter perforations 14 (see Louw, fig. 2), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Louw as modified by Mahurkar with a perforation at a location similar to that of Ellard because such a modification would amount to a design choice. It has previously been held that shifting location of parts is not patentable--*See In re Japikse, 181 F. 2d 1019, 1023, 86 USPQ 70, 73 (CCPA 1950).*

In regards to claims 32 and 44, Louw as modified by Mahurkar discloses a device, as described above, that teaches all the limitations of the claim except Louw as modified by Mahurkar does not teach a return device. However, Ellard discloses a device comprising a return device 40 wherein said return device is a spring (see fig.

2). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Louw as modified by Mahurkar with a return device similar to that of Ellard in order to automatically force the plunger back into its initial position (see Ellard, column 3/lines 30-33 & 38-42).

5. Claims 27-28, 31 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Louw ('345) in view of Mahurkar ('921) in view of Sundberg (US Patent No. 5,494,044).

Louw as modified by Mahurkar discloses a device, as described above, that teaches all the limitations of the claim except that it does not further comprise a filter. Sundberg discloses a syringe with a cell filter 17 located in the barrel 10 in the fluid flow path to and from the fluid chamber through the hollow catheter 15; the cell filter 17 is adapted to substantially remove cells and cellular debris from a fluid in said fluid flow path (see column 5/lines 34-35, 57-60). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Louw as modified by Mahurkar with a filter similar to that of Sundberg in order to perform in-vivo separation of bodily fluids from cells (i.e. simultaneous collection and filtering operations).

6. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Louw ('345) in view of Mahurkar ('921) further in view of Sundberg ('044) as applied to claim 27 above, even further in view of Schindler et al. (US Patent No. 4,265,249).

The device of Louw as modified by Mahurkar as furthermodified by Sundberg discloses all the limitations of the claim except that the filter is not located in the hollow

catheter. Schindler et al. disclose a catheter device wherein a filter is positioned in hollow catheter. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Louw as modified by Mahurkar as modified by Sundberg with a filter located in the hollow catheter in order to remove the cells from the body fluid directly inside the body of the patient (column 1/lines 61-64).

7. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Louw ('345) in view of Mahurkar ('921) in view of Sundberg ('044) as applied to claim 27 above, further in view of Baidwan et al. (US Patent No. 5,238,003).

The device of Louw as modified by Mahurkar as modified by Sundberg discloses all the limitations of the claim except that the filter is not located in the plunger. Baidwan et al. disclose a syringe with a filter located in the plunger (see figs. 1 & 2). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Louw as modified by Mahurkar as modified by Sundberg with a filter located in the plunger, which controls the volume of fluid to be collected, so as to maximize the capacity of the fluid chamber of the syringe (i.e. when the filter is located in the barrel, less fluid can be collected with a similar size syringe compared to when the filter is located in the plunger) (see column 1/lines 18-22).

8. Claims 37-39 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Louw ('345) in view of Mahurkar ('921) further in view of Johnson (US Patent No. 4,744,789).

Louw discloses a device capable of collection of a fluid sample, comprising a flexible, hollow, elongate catheter 1 extending through an opening, said catheter 1 being sufficiently flexible so as to be capable of bending and follow the conformation of an internal cavity upon encountering walls of said cavity during insertion into said cavity without damaging tissue of said cavity, said catheter 1 further being in operative engagement with a manifold 3 for axial movement to extend and retract the catheter 1 on axial movement of the manifold 3, and said catheter 1 being in fluid communication with the fluid chamber to provide a fluid flow path to and from the fluid chamber through the hollow catheter 1 (see figs. 1-2; column 2/lines 35-53; column 3/lines 18-24; column 4/lines 23-27; column 5/lines 15-30 & 65-68; column 6/lines 1-4) .

Louw discloses a device, as described above, that teaches all the limitations of the claim except that Louw does not teach a device comprising a barrel and a plunger. However, Mahurkar discloses a device as follows:

Mahurkar discloses a device capable of collection of a fluid sample, comprising a barrel 10 having an opening 15 at one end thereof, a plunger 11 operable axially within the barrel 10, said barrel 10 and said plunger 11 defining a fluid chamber having a volume which varies on axial movement of the plunger 11 within the barrel 10 and a flexible catheter 13, wherein one end of said catheter 13 is attached to said plunger 11 and the end of said catheter 13 is remote from the plunger 11 (see figs. 4 & 5).

Since Louw discloses a catheter device for sampling of endometrial tissue wherein the catheter is steerable through axial (i.e. by way of the manifold 3) and

rotational motions (i.e. by way of the guide 5) (see fig. 1; column 4/lines 23-27; column 5/lines 41-44) and Mahurkar teaches a catheter device that is steerable through axial and rotational motions (see figs. 4-5), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Louw with a steering mechanism similar to that of Mahurkar since both mechanisms help stabilize the catheter during its insertion into the internal cavity (see Louw, column 4/lines 35-48). Moreover, merely exchanging steering mechanisms amount to a design choice. It has previously been held that changing aesthetic design is not patentable--See In re Seid, 161 F.2d 229, 231, 73 USPQ 431, 433 (CCPA 1947).

In regards to claims 37-39 and 43, Louw as modified by Mahurkar teaches locating a distal end of a flexible hollow, elongate catheter 1 at an opening of an internal cavity (i.e. uterus) and washing (i.e. lavage) and collecting fluid from the cavity; wherein said catheter is flexible and follows the conformation of said internal cavity during retracting and penetrating (see Louw, column 2/lines 35-53; column 4/lines 23-27; column 5/lines 65-68; column 6/lines 1-4) except that Louw as modified by Mahurkar does not teach the steps of simultaneously moving the catheter and washing and/or collecting fluid from the internal cavity. However, Johnson discloses a method of injecting fluid into an internal body cavity comprising the step of penetrating of the internal body cavity and injecting the fluid during said penetrating (see figs. 11A-B). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Louw as modified by Mahurkar with a method step similar to that of Johnson in order to change the point of

application of the injected or collected material as the material is being injected or collected so as to provide a desirable distribution of the injected or collected material (see Johnson, column 5/lines 22-42).

9. Claims 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Louw ('345) in view of Mahurkar ('921) further in view of Johnson ('789) even further in view of Sundberg ('044).

Louw as modified by Mahurkar as further modified by Johnson discloses a method, as described above, that teaches all the limitations of the claim including the collection of uterine cells except that Louw as modified by Mahurkar as further modified by Johnson does not specifically teach the steps of filtering of the fluid sample. However, Sundberg discloses a method as follows:

Regarding claim 40, Sundberg discloses a method, as described above, comprising the further step of substantially separating out the fluid sample from the cells and cellular debris (see column 3/lines 1-14; column 5/lines 34-35, 57-60).

Regarding claim 41, Sundberg discloses a method, as described above, wherein a sample of cells or cellular debris is simultaneously collected at the opening of the internal cavity (see column 3/lines 1-14; column 5/lines 34-35, 57-60).

Since both Sundberg and Louw as modified by Mahurkar as further modified by Johnson discloses collecting a sample comprising a mixture of fluid and cells from the uterus, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Louw as modified by Mahurkar as further modified by Johnson with method steps similar those of

Sundberg in order to continuously perform in-vivo separation of fluids from cells (i.e. simultaneous collection and filtering operations).

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 4,182,328 to Bolduc et al. discloses a dispensing instrument and method.

US Patent No. 4,088,135 to O'Neill discloses a balloon catheter with coaxial activating syringe.

US Patent No. 6,146,373 to Cragg et al. discloses a catheter system and method for injection of a liquid embolic composition.

US Patent No. 5,624,399 to Ackerman discloses a catheter having an intracervical intrauterine balloon.

US Patent No. 5,338,297 to Kocur et al. discloses a cervical canal balloon catheter.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RTT

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